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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,966	09/23/2003	Dong Xie	63024.000002	7892

21967 7590 11/21/2008
HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
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WASHINGTON, DC 20006-1109

EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

MAIL DATE	DELIVERY MODE
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11/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,966	Applicant(s) XIE ET AL.	
	Examiner Jeffrey S. Parkin	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 6 is/are allowed.
- 6) ☒ Claim(s) 5 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Docket No.: 63024.000002

Applicants: Xie, D., and H. Jiang

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Detailed Office Action

Status of the Claims

The FINALITY of the last office action is hereby withdrawn in response to the telephonic interview conducted with applicants' representatives (Robert C. Lampe III (Reg. No. 51,194) and Laurence H. Posorske, Ph.D., (Reg. No. 34,698)) on 31 January, 2008. Claims 1, 5, 6, and 11 are pending in the instant application.

Allowable Subject Matter

Claims 1 and 6 appear to be free of the prior art of record and are allowable.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The claim is directed toward "derivatized"

peptides having the specified sequence identifiers. The term "derivatized" is vague and indefinite because it fails to set forth the salient structural characteristics of any given polypeptide. For instance, what type of modification is encompassed by the term "derviatized". Does the peptide contain single or multiple amino acid substitutions, additions, or deletions? Have various reactive groups on the polypeptide been modified to incorporate a linker? Although the term is defined in the specification (e.g., see page 7), nevertheless, applicants are reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Geuns*, 988 F.2d 1181, 26 U.S.P.Q.2d 1057 (Fed. Cir. 1993). Amendment of the claim language to recite peptide sequences that have been modified to include a coupling group (e.g., a maleimide linker) would be remedial.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 5 is rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Barney *et al.* (2001). Barney and colleagues provide an isolated polypeptide consisting of SEQ ID NO.: 12 (see SEQ ID NO.: 1071, cols. 547/548). This polypeptide

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has the same amino acid sequence as the FB010M peptide of SEQ ID NO.: 12.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claim 11 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Barney *et al.* (2001) in view of Bridon *et al.* (2000). The claim is directed toward an isolated polypeptide consisting of SEQ ID NO.: 3 wherein said sequence has been

modified to incorporate a lysine at aa 13 (E:K) and attaching a coupling group to the lysine, or attaching a coupling group to a lysine at the C-terminus. Barney and colleagues provide a polypeptide that is identical to SEQ ID NO.: 3 with one exception. This peptide contains a conservative amino acid substitution (leucine as opposed to isoleucine) at position 12. However, since this is a conservative amino acid substitution it would not be expected to alter the antiviral activities of the polypeptide to any appreciable extent (see Bridon *et al.*, p. 16). Thus, one of ordinary skill in the art would reasonably assume that these polypeptides are functional equivalents and obvious variants of one another. Barney and colleagues do not explicitly discuss incorporating a lysine at aa 13 (E:K) and attaching a coupling group to the lysine, or attaching a coupling group to a lysine at the C-terminus.

However, Bridon *et al.* (2000) disclose the preparation of modified polypeptides wherein said polypeptides comprise a maleimide linker attached to the ϵ -amine of lysine. The authors provide a detailed discussion about preparing conjugates and identifying suitable amino acids that are reactive with NHS esters (see pp. 16-21). The authors also note that modified polypeptides carrying maleimide linkers can be conjugated to various carrier molecules thereby prolonging their circulating half-life.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to modify the antiviral polypeptide of Barney *et al.* (2001), to incorporate a lysine residue and maleimide linker at the amino-

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terminus, carboxyl-terminus, or internally (provided that it does not interfere with the antiviral activity of the polypeptide). The incorporation of such a modification would reasonably be expected to facilitate polypeptide coupling to a carrier molecule which would provide favorable pharmacological profiles.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Bruce R. Campell, Ph.D., can be reached at (571) 272-0974. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

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Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin/

Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

08 November, 2008

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Appendix A

Sequence Search Results for SEQ ID NO.: 12:

US-09-082-279B-1071

; **Sequence 1071, Application US/09082279B**

; **Patent No. 6258782**

; GENERAL INFORMATION:

; APPLICANT: Barney, Shawn

; APPLICANT: Guthrie, Kelly

; APPLICANT: Merutka, Gene

; APPLICANT: Anwer, Mohmed

; APPLICANT: Lambert, Dennis

; TITLE OF INVENTION: HYBRID POLYPEPTIDES WITH ENHANCED

; TITLE OF INVENTION: PHARMACOKINETIC PROPERTIES

; FILE REFERENCE: 7872-043

; CURRENT APPLICATION NUMBER: US/09/082,279B

; CURRENT FILING DATE: 1998-05-20

; NUMBER OF SEQ ID NOS: 1515

; SOFTWARE: FastSEQ for Windows Version 3.0

; SEQ ID NO 1071

; LENGTH: 39

; TYPE: PRT

; ORGANISM: Artificial Sequence

; FEATURE:

; OTHER INFORMATION: Core polypeptide

US-09-082-279B-1071

Query Match 99.5%; Score 213; DB 2; Length 39;
Best Local Similarity 97.4%; Pred. No. 1.8e-19;
Matches 38; Conservative 0; Mismatches 1; Indels
0; Gaps 0;

Qy ('966) 1 WQEWKQKITALLXQAQIQQEKNEYELQKLDKWASLWEWF 39

|||||

Db ('782) 1 WQEWKQKITALLEQAQIQQEKNEYELQKLDKWASLWEWF 39

X can be any amino acid.

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Appendix B

Sequence Search Results for SEQ ID NO.: 3:

US-09-082-279B-1071

; **Sequence 1071, Application US/09082279B**

; **Patent No. 6258782**

; GENERAL INFORMATION:

; APPLICANT: Barney, Shawn

; APPLICANT: Guthrie, Kelly

; APPLICANT: Merutka, Gene

; APPLICANT: Anwer, Mohmed

; APPLICANT: Lambert, Dennis

; TITLE OF INVENTION: HYBRID POLYPEPTIDES WITH ENHANCED

; TITLE OF INVENTION: PHARMACOKINETIC PROPERTIES

; FILE REFERENCE: 7872-043

; CURRENT APPLICATION NUMBER: US/09/082,279B

; CURRENT FILING DATE: 1998-05-20

; NUMBER OF SEQ ID NOS: 1515

; SOFTWARE: FastSEQ for Windows Version 3.0

; SEQ ID NO 1071

; LENGTH: 39

; TYPE: PRT

; ORGANISM: Artificial Sequence

; FEATURE:

; OTHER INFORMATION: Core polypeptide

US-09-082-279B-1071

Query Match 99.1%; Score 217; DB 2; Length 39;
Best Local Similarity 97.4%; Pred. No. 6.6e-19;
Matches 38; Conservative 1; Mismatches 0; Indels
0; Gaps 0;

Qy 1 WQEWKQKITALIEQAQIQQEKNEYELQKLDKWASLWEWF 39

|||||||:|||||||

Db 1 WQEWKQKITALLEQAQIQQEKNEYELQKLDKWASLWEWF 39

The only difference is a conservative substitution between I:L at aa 12.